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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,466	08/16/2001	Larry D. Paskar	39868/25551	3794

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EXAMINER

BOCKELMAN, MARK

ART UNIT PAPER NUMBER

3762

DATE MAILED: 11/06/2003

15 #

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,466

Applicant(s)

PASKAR, LARRY D.

Examiner

Mark W Bockelman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-16 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 23, 25, 27 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 19-22, 24, 26, 28-29 and 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of invention II claims 10-16, 19-22, 24, 26, 28-29 and 31-34 in Paper No. 14 is acknowledged.
2. Claims 1-7, 23, 25, 27, 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention I, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.14.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the relative radii of curvature between the outer sheath and the inner element of claim 14 must be shown or the feature(s) canceled from the claim(s). The examiner does not readily find support for these claimed features in the current drawings and it is unclear as to which drawing(s) are being relied upon for support. The examiner requests applicant to diagram on an existing drawing the two radii of curvature. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

3. Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz. USPN 5,267,982 (alone or in view of either Voda USPN 5,445,625 or Weldon USPN 5,195,990 and Cho USPN 5,109,830).

Sylvanowicz teaches an inner catheter illustrated in figure 11 (surgical element) that is situated within an outer catheter figure 10, each with preformed curves. The entire assembly of catheters is to be inserted into the body and Sylvanowicz teaches an element 30 that maybe used to apply an adjustable constricting force against the inner catheter to effect sealing. This of course also applies a friction grip against the inner catheter that would tend to inhibit rotation in an identical fashion as applicant's fixing means shown as element 103 of applicant's specification.. Sylvanowicz teaches that with regard to his two different catheter configurations, the configuration in figs 1-8 has in at least one embodiment that is a standard Judkins left coronary catheter structure or a modified left Judkin structure (figs 9-14) wherein the angle defined by bend 62 is slightly larger. The examiner contends that when used as in the same manner as a Judkins left catheter, the assembly of inner and outer catheter provides a planar assembly. The examiner cites Voda USPN 5,445,625 figures 1a -1d as prior figure demonstrating at the time as a standard left Judkins coronary catheter known at the time of the Sylvanowicz filing and notes that the structure demonstrates a planar curve

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at the bend. The examiner thus concludes that the Sylvanowicz outer sheath possesses a planar configuration prior to insertion into the body. The examiner also concludes that if applicant's apparent method steps in apparatus claim 1 are viewed as intended use the Sylvanowicz catheter assembly is fully capable of performing the function. The examiner also notes that nothing in the Sylvanowicz disclosure suggests that the planar configuration would be compromised in the aortic root region. While the disclosure shows a single point on the catheter that engages the wall of the ascending aorta opposite the left coronary artery, such a single point of contact could not conceivably alter the outer catheter curve in a nonplanar manner. Even if the single point engaged the curved portion orthogonal to the plane of the curve (which it does not), the curve would still lie in a plane although it may no longer contain the proximal segment 52. Applicant's portion of his specification that is dedicated to the out of plane configuration fails to explicitly state any particular type of medical method for any period of time and thus the examiner concludes that applicant's medical method is merely the catheterization of the vessel. Sylvanowicz teaches at least applicant's medical method as well as others such as the introduction of contrast media.

As noted above, the Sylvanowicz catheter assumes a Judkins left coronary shape while in the configuration of figure 12 which as demonstrated above, would provide curve 60 in a planar state. Inner catheter member 57 would then be either positioned to be aligned in said plane or alternatively be oriented at an angle that would thus meet applicant's method claim. Assuming that it does not already meet applicant's limitation, Sylvanowicz teaches that the inner catheter is rotated with respect to the

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outer catheter so as align the inner catheter with the right coronary ostia (see column 7 lines 50-65). Thus, at some point, the inner catheter will be "positioned" in an out of plane configuration including when the right coronary ostia has been intubated and sealing gasket while providing a sealing constriction also provides friction so as to fix the inner catheter in place with respect to the outer catheter member. It is impossible for Sylvanowicz to change the combination catheter configuration from figure 12 to that which is shown in figure 14 since Sylvanowicz teaches that only the inner catheter need be rotated (column 7 lines 61-63). Since the examiner considers. On the other hand, Sylvanowicz does not explicitly teach that the inner catheter is "positioned" in a "fixed" manner so that the inner catheter curve is fixed out of plane with respect to the outer catheter as specified in claim.

While the examiner notes that Sylvanowicz does use the word "fixing" or fixed in his various catheter arrangements, the examiner considers it inherent that the constrictional frictional forces applied to Sylvanowicz to prevent leakage would be sufficient to prevent the inner member from shifting while attempting to intubate as well as inject dye into each of the coronary arteries. Otherwise it would have been obvious to prevent rotation by tightening the Sylvanowicz sealing gasket after catheter placement as taught by Cho USPN 5,109,830, which uses a similar device for "locking" an inner element after it has been placed at the desired location. The curves in the Sylvanowicz catheter are remotely controllable by moving the inner catheter longitudinally with respect to the outer catheter. In regard to new claims 24, 26, 28, 31-32, the gripping member proximally fixes the inner catheter in same way that applicant's

disclose. With respect to claim 32, it is clear from Voda that the left judkins shape may have a modified so that the distal tip segment is out of plane with the catheter body. To have initially accessed the left coronary artery in the Sylvanowicz method with an out of plane configuration followed by and out of plane right coronary artery configuration would have been obvious.

4. Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view of D'Amelio et al USPN 4,659,195, Ueda 4,617,914 (US Patent class 600/148), Cho USPN 5109,830 and Takahashi reference manual.

Petruzzi et al teach an inner surgical element comprising a catheter with a preformed curve 56 along with a surgical instrument disposed therein, and both further disposed in an outer catheter in the form of a duodenoscope. As was well known in the art, such scoped has a two way control element 42 and 42' that allow two plane bending to traverse the alimentary tract including the small intestine region. If not apparent to one of ordinary skill in the art that Petruzzi et al uses such two plane direction it would have been obvious to D'Amelio et al USPN 4,659,195. As can be seen in figure 1 of Petruzzi, the device of Petruzzi is used to position catheter member 56 into the ampulla of Vater which is located on the rear wall of the duodenum in a highly curved region which tends to curve towards the front of a person near the stomach and back towards the rear as well as to the left side approaching the ileum. This relative location of the

ampulla of Vater is shown to some extent by Petruzzi but can better be seen in the three dimensional figure attached to this office action (Takahashi "Atlas of the Human Body"). As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right manner relative to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner surgical element 56 60 be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the the ampulla of Vater. In terms of rotationally fixing the inner surgical element, It was well known to stabilize endoscopic devices including rotationally fixing and sealing the inner surgical element relative to the outer sheath body as disclosed by Cho. Petruzzi shows a first and second configuration in figure 3 that are used in catheterizing the duodenum and later the ampulla of Vater. The bends in the Petruzzi catheter as shown in figure 11 are both within 3 lengths of the smaller radii of curve.

5. Claims 10-16 and 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al USPN 4,430,083 in view of Sylvanowicz, Cho and Takahashi page 42. Ganz et al shows in figure 12 and 13, methods for catheterizing two passageways of the lower circumflex branch using a catheter using a planar outer catheter 11a (column 7 lines 7-20) and an inner rotatable catheter 105. The figures 12 and 13 appear to show an out of plane configurations as the inner

catheter 105 or 105b are shown to access each of the two branches. Takahashi is presented as showing how the branches go off in different directions requiring such an out of plane configuration. While Ganz does not teach rotationally fixing the inner catheter, it would have been obvious in view of Cho and Sylvanowicz to provide a sealing as well as locking force to maintain placement of the catheter during drug delivery. The curves on the inner catheter are remotely controllable by rotating and sliding the catheters with respect to each other in a manner as taught by Sylvanowicz or otherwise obvious. In regard to those claims that require first and second out of plane configurations (claim 28) the examiner considers it obvious to provide the first treatment of figure 12 followed by a second treatment in figure 13 and in view of Sylvanowicz, to use the the same inner catheter rotated

6. Claims 10-16 and 19, 24, 26, 28, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho USPN 5,109,830 in view of Ueda (class 600/148) and Takahashi (page 66). Cho teaches a method of accessing the various ducts including pancreatic, bile, common etc. and shows such an arrangement in figure 7. While figure 7 shows a duodenoscope 51 having a bent configuration as well as an inner surgical element 3, better seen in figure 6, also having a preformed bend, it is unclear as to whether the duodenoscope has a fixed curve therein. The examiner cites Ueda as showing that it was known to use a braking mechanism to retain or fix curve regions in an endoscope. To have provide the bent configuration of element 51 with a braking tension wire would have been obvious to those of ordinary skill in the art particularly as

taught by UEDA and the examiner's citation of the class/subclass schedule for 600/148.

As can be seen in Takahashi, the gall bladder as well has hepatic duct as well as common bile duct all feed behind the upper colon thereby making it a necessity to form an out of plane configuration to access these members. The examiner considers applicant's claims to be obvious in view of the various configurations of the ducts.

7. Claims 21, 22 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho USPN 5,109,830 in view of Ueda (class 600/148) and Takahashi (page 66) and Komi USPN 4,979,496. To have reformed the catheter in first and second out of plane configurations so as to access both the pancreatic and bile duct as taught by Komi USPN 4,979,496 would have been obvious.

8. Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amelio et al USPN or Costella in view of D'Amelio each in further view of Ueda (600/148) and Cho. D'Amelio teach inner and outer articulating devices that may be locked so as to prevent rotation and translation in a similar fashion as Cho. It is customary to provide brakes so as to maintain articulated curves such as demonstrated by Ueda and the US patent classification system. Applicant merely recites a general method of configuring different shapes that would be apparent to those familiar in the art of endoscopy.

Response to Arguments

9. Applicant's arguments filed 4-15-03 have been fully considered but they are not persuasive. First, the examiner notes that the examiner in the office action mailed 11-15-02 objected to the drawings as not showing the features of claim 14 with respect to the relative radii of the first and second curves. Applicant has failed to address this issue in the response of 4-15-03.

10. With respect to applicant's rebuttal of the rejection of claims under Sylvanowicz.USPN 5,267,982 (alone or in view of either Voda USPN 5,445,625 or Weldon USPN 5,195,990 and Cho USPN 5,109,830) applicant seems to believe that the examiner is confined in his interpretation of the art to language used by the Sylvanowicz reference in describing his catheter. For some reason applicant feels that the examiner is bound in art interpretation to equate the Sylvanowicz term "distal segment" with applicant's claimed "distal end portion" and to conclude that a distal end segment 62 cannot be interpreted to be part of a "distal end portion" which includes curved portion 60 of the device. The examiner disagrees and does not find that he has violated any rules of art interpretation in accordance with the MPEP. The examiner also notes Voda 5,445,625 discusses "distal end portions" which are comprised of various "segments" therein. In addition, applicant seems to feel that the inner catheter described as pointing towards the ostia prior to insertion describes something that prevents the examiner from concluding that an out of plane structure exists. The examiner does not follow applicant's line of reasoning but notes that prior to insertion the distal tip of the

inner catheter has to point in a direction that is toward the ostia while it is displaced in the aortic root and that it could potentially point to it from many directions but that once intubated is going align with the coronary artery passages.

Applicant provides no new arguments regarding the "Petruzzi" rejection other than those already addressed by the examiner

Applicant's arguments concerning the "Ganz" rejection appears to be addressed to two issues, those claims that require two different out of plane configurations and to those claims that require "proximal fixing". The examiner has cited Sylvanowicz and Cho to address the issue of proximal fixing and maintains that such "fixing" is conventional in nature to prevent the inner catheter and outer catheter from slipping out of position once the proper placement has been made as well as preventing leakage. The applicant's point concerning catheters 105 and 105b being different catheters is well taken and the examiner has clarified his position in view of the Sylvanowicz disclosure.

In regard to the rejections under the "Cho" rejections, applicant apparently feels that the Ueda and Cho are not properly combinable due to a lack of motivation. The examiner disagrees, to show old and conventional structure to parts of endoscopes that the Cho reference utilizes is a proper demonstration of obviousness given they are both in the same field of endeavor and are utilized in the same capacity as internal visual inspection systems.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-305-3591 for regular communications and (703)-306-4520 for After Final communications.

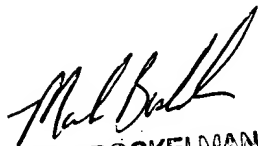
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

October 5, 2003


MARK BOCKELMAN
PRIMARY EXAMINER